General

Guideline Title

Management of adult patients with ascites due to cirrhosis: update 2012.

Bibliographic Source(s)

Runyon BA. Management of adult patients with ascites due to cirrhosis: update 2012. Alexandria (VA): American Association for the Study of Liver Diseases; 2013 Feb. 27 p. [214 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Runyon BA, AASLD Practice Guidelines Committee. Management of adult patients with ascites due to cirrhosis: an update. Hepatology. 2009 Jun;49(6):2087-107. [174 references]

Regulatory Alert

FDA Warning/Regulatory Alert

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- May 12, 2016 – Fluoroquinolone Antibacterial Drugs : The U.S. Food and Drug Administration (FDA) is advising that the serious side effects associated with fluoroquinolone antibacterial drugs generally outweigh the benefits for patients with sinusitis, bronchitis, and uncomplicated urinary tract infections who have other treatment options. For patients with these conditions, fluoroquinolones should be reserved for those who do not have alternative treatment options.

Recommendations

Major Recommendations

The grading system for the class of recommendations (I, II, IIa, IIb, III) and the levels of evidence (A–C) are defined at the end of the "Major Recommendations" field.

Evaluation and Diagnosis

1. Diagnostic abdominal paracentesis should be performed and ascitic fluid should be obtained from inpatients and outpatients with clinically

apparent new-onset ascites (Class I, Level C).
2. Since bleeding is sufficiently uncommon, the routine prophylactic use of fresh frozen plasma or platelets before paracentesis is not recommended (Class III, Level C).

Ascitic Fluid Analysis and Differential Diagnosis

3. The initial laboratory investigation of ascitic fluid should include an ascitic fluid cell count and differential, ascitic fluid total protein, and serum-ascites albumin gradient (SAAG) (Class I, Level B).
4. If ascitic fluid infection is suspected, ascitic fluid should be cultured at the bedside in aerobic and anaerobic blood culture bottles prior to initiation of antibiotics (Class I, Level B).
5. Other studies of ascitic fluid can be ordered based on the pretest probability of disease (Refer to Table 3 in the original guideline document for ascitic fluid laboratory data) (Class IIa, Level C).
6. Testing serum for cancer antigen 125 (CA125) is not helpful in the differential diagnosis of ascites. Its use is not recommended in patients with ascites of any type (Class III, Level B).

Treatment of Ascites

7. Patients with ascites who are thought to have an alcohol component to their liver injury should abstain from alcohol consumption (Class I, Level B).
8. Baclofen can be given to reduce alcohol craving and alcohol consumption in patients with ascites in the setting of alcoholic liver disease (Class IIb, Level C).
9. First-line treatment of patients with cirrhosis and ascites consists of sodium restriction (88 mmol per day [2000 mg per day], diet education) and diuretics (oral spironolactone with or without oral furosemide) (Class IIa, Level A).
10. Fluid restriction is not necessary unless serum sodium is less than 125 mmol/L (Class III, Level C).
11. Vaptans may improve serum sodium in patients with cirrhosis and ascites. However their use does not currently appear justified in view of their expense, potential risks, and lack of evidence of efficacy in clinically meaningful outcomes (Class III, Level A).
12. An initial therapeutic abdominal paracentesis should be performed in patients with tense ascites. Sodium restriction and oral diuretics should then be initiated (Class IIa, Level C).
13. Diuretic-sensitive patients should preferably be treated with sodium restriction and oral diuretics rather than with serial paracenteses (Class IIa, Level C).
14. Use of angiotensin converting enzyme inhibitors and angiotensin receptor blockers in patients with cirrhosis and ascites may be harmful, must be carefully considered in each patient, monitoring blood pressure and renal function (Class III, Level C).
15. The use of nonsteroidal anti-inflammatory drugs should be avoided in patients with cirrhosis and ascites, except in special circumstances (Class III, Level C).
16. Liver transplantation should be considered in patients with cirrhosis and ascites (Class I, Level B).

Refractory Ascites

17. The risks versus benefits of beta blockers must be carefully weighed in each patient with refractory ascites. Systemic hypotension often complicates their use. Consideration should be given to discontinuing or not initiating these drugs in this setting (Class III, Level B).
18. The use of angiotensin converting enzyme inhibitors and angiotensin receptor blockers should be avoided in patients with refractory ascites. Systemic hypotension often complicates their use (Class III, Level B).
19. Oral midodrine has been shown to improve clinical outcomes and survival in patients with refractory ascites; its use should be considered in this setting (Class IIa, Level B).
20. Serial therapeutic paracenteses are a treatment option for patients with refractory ascites (Class I, Level C).
21. Post-paracentesis albumin infusion may not be necessary for a single paracentesis of less than 4 to 5 L (Class I, Level C).
22. For large-volume paracenteses, an albumin infusion of 6-8 g per liter of fluid removed appears to improve survival and is recommended (Class IIa, Level A).
23. Referral for liver transplantation should be expedited in patients with refractory ascites, if the patient is otherwise a candidate for transplantation (Class IIa, Level C).
24. Transjugular intrahepatic portosystemic stent-shunt (TIPS) may be considered in appropriately selected patients who meet criteria similar to those of published randomized trials (Class I, Level A).
25. Peritoneovenous shunt, performed by a surgeon or interventional radiologist experienced with this technique, should be considered for patients with refractory ascites who are not candidates for paracenteses, transplant, or TIPS (Class IIb, Level A).

Spontaneous Bacterial Peritonitis (SBP)

26. Patients with ascites admitted to the hospital should undergo abdominal paracentesis. Paracentesis should be repeated in patients (whether in the hospital or not) who develop signs or symptoms or laboratory abnormalities suggestive of infection (e.g., abdominal pain or tenderness, fever, encephalopathy, renal failure, acidosis, or peripheral leukocytosis) (Class I, Level B).
27. Patients with ascitic fluid polymorphonuclear leukocyte (PMN) counts greater than or equal to 250 cells/mm^3 (0.25 x 10^9/L) in a community-acquired setting in the absence of recent B-lactam antibiotic exposure should receive empiric antibiotic therapy, e.g., an intravenous third-generation cephalosporin, preferably cefotaxime 2 g every 8 hours (Class I, Level A).
28. Patients with ascitic fluid PMN counts greater than or equal to 250 cells/mm^3 (0.25 x 10^9/L) in a nosocomial setting and/or in the presence of recent B-lactam antibiotic exposure should receive empiric antibiotic therapy based on local susceptibility testing of bacteria in patients with cirrhosis (Class IIa, Level B).
29. Oral ofloxacin (400 mg twice per day) can be considered a substitute for intravenous cefotaxime in inpatients without prior exposure to quinolones, vomiting, shock, grade II (or higher) hepatic encephalopathy, or serum creatinine greater than 3 mg/ dL (Class IIa, Level B).
30. Patients with ascitic fluid PMN counts less than 250 cells/mm^3 (0.25 x 10^9/L) and signs or symptoms of infection (temperature >100º F or abdominal pain or tenderness) should also receive empiric antibiotic therapy, e.g., intravenous cefotaxime 2 g every 8 hours, while awaiting results of cultures (Class I, Level B).
31. When the ascitic fluid of a patient with cirrhosis is found to have a PMN count greater than or equal to 250 cells/mm^3 (0.25 x 10^9/L) and there is high suspicion of secondary peritonitis, it should also be tested for protein, lactate dehydrogenase (LDH), glucose, Gram's stain, carcinoembryonic antigen, and alkaline phosphatase to assist with the distinction of SBP from secondary peritonitis. Computed tomographic scanning should also be performed (Class IIa, Level B).
32. Patients with ascitic fluid PMN counts greater than or equal to 250 cells/mm^3 (0.25 x 10^9/L) in a nosocomial setting and/or in the presence of recent B-lactam antibiotic exposure and/or culture an atypical organism(s) or have an atypical clinical response to treatment, should undergo a follow-up paracentesis after 48 hrs of treatment to assess the response in PMN count and culture (Class IIa, Level C).
33. Patients with ascitic fluid PMN counts greater than or equal to 250 cells/mm^3 (0.25 x 10^9/L) and clinical suspicion of SBP, who also have a serum creatinine >1 mg/dL, blood urea nitrogen >30 mg/dL, or total bilirubin >4 mg/dL should receive 1.5 g albumin per kg body weight within 6 hours of detection and 1.0 g/kg on day 3 (Class IIa, Level B).

Prevention of SBP

34. Intravenous ceftriaxone for 7 days or twice-daily norfloxacin for 7 days should be given to prevent bacterial infections in patients with cirrhosis and gastrointestinal hemorrhage (Class I, Level A). Perhaps parenteral antibiotic, while the patient is bleeding and oral antibiotic after oral intake is resumed, for a total of 7 days, is a practical treatment regimen.
35. Patients who have survived an episode of SBP should receive long-term prophylaxis with daily norfloxacin (or trimethoprim/sulfamethoxazole) (Class I, Level A).
36. In patients with cirrhosis and ascites, long-term use of norfloxacin (or trimethoprim/sulfamethasoxazole) can be justified if the ascitic fluid protein <1.5 g/dL along with impaired renal function (creatinine ≥1.2, blood urea nitrogen [BUN] ≥25 or serum sodium [Na] ≤130) or liver failure (Child score ≥9 and bilirubin ≥3) (Class I, Level A).
37. Intermittent dosing of antibiotics to prevent bacterial infections may be inferior to daily dosing (due to the development of bacterial resistance) and thus daily dosing should preferentially be used (Class IIb, Level C).

Hepatorenal Syndrome

38. Urinary biomarkers such as neutrophil gelatinase associated lipocalin may assist in the differential diagnosis of azotemia in patients with cirrhosis (Class IIa, Level B).
39. Albumin infusion plus administration of vasoactive drugs such as octreotide and midodrine should be considered in the treatment of type I hepatorenal syndrome (Class IIa, Level B).
40. Albumin infusion plus administration of norepinephrine should also be considered in the treatment of type I hepatorenal syndrome, when the patient is in the intensive care unit (Class IIa, Level A).
41. Patients with cirrhosis, ascites, and type I or type II hepatorenal syndrome should have an expedited referral for liver transplantation (Class I, Level B).

Umbilical Hernias in Patients with Cirrhosis and Ascites

42. The risks versus benefits of hernia repair must be weighed carefully in patients with cirrhosis and ascites. Elective repair can be performed during or after liver transplantation (Class IIa, Level C).
43. Elective repair of a hernia in a patient with cirrhosis is best performed after ascites has been controlled by medical treatment, the patient's overall condition has been optimized, and a multidisciplinary approach with consideration of perioperative TIPS is utilized (Class IIa, Level

C).

44. Emergent repair of a strangulated or perforated umbilical hernia is best performed by a surgeon who is experienced in the care of patients with cirrhosis (Class IIa, Level C).

Hepatic Hydrothorax

45. Chest tube insertion is contraindicated in patients with hepatic hydrothorax (Class III, Level B).
46. First-line therapy of hepatic hydrothorax consists of dietary sodium restriction and diuretics (Class IIa, Level B).
47. TIPS can be considered as second-line treatment for hepatic hydrothorax, once it becomes refractory (Class IIb, Level B).

Cellulitis

48. Cellulitis can explain pain and fever in patients with cirrhosis and ascites and should be treated with diuretics and antibiotic(s) (Class IIb, Level B).

Percutaneous Endoscopic Gastrostomy

49. Percutaneous endoscopic gastrostomy should be avoided in patients with cirrhosis and ascites (Class IIb, Level B).

Definitions:

Levels of Evidence

Level A Data derived from multiple randomized clinical trials or meta-analyses

Level B Data derived from a single randomized trial, or nonrandomized studies

Level C Only consensus opinion of experts, case studies, or standard-of-care

Grading System for Recommendations

Class I Conditions for which there is evidence and/or general agreement that a given diagnostic evaluation, procedure or treatment is beneficial, useful, and effective

Class II Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a diagnostic evaluation, procedure, or treatment

Class IIa Weight of evidence/opinion is in favor of usefulness/efficacy

Class IIb Usefulness/efficacy is less well established by evidence/opinion

Class III Conditions for which there is evidence and/or general agreement that a diagnostic evaluation, procedure/treatment is not useful/effective and in some cases may be harmful

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Ascites due to liver cirrhosis

Guideline Category

Diagnosis

Evaluation

Management

Prevention

Treatment

Clinical Specialty

Family Practice

Gastroenterology

Internal Medicine

Radiology

Surgery

Intended Users

Physicians

Guideline Objective(s)

To provide a data-supported approach to management of patients with ascites due to cirrhosis

Target Population

Adult patients with clinically detectable ascites due to cirrhosis

Note:

> Although the general approach may be applicable to children, the pediatric database is much smaller and there may be unanticipated differences between adults and children.
> Patients with ascites detected only by imaging modalities but not yet clinically evident are excluded because of the lack of published information regarding the natural history of this entity.

Interventions and Practices Considered

Assessment/Diagnosis

1. Abdominal paracentesis
2. Ascitic fluid analysis and differential diagnosis
3. Other studies of ascitic fluid (as indicated)

Management/Treatment

1. Abstinence from alcohol consumption
2. Baclofen
3. Sodium restriction, diet education, diuretics (oral spironolactone with or without oral furosemide)
4. Therapeutic abdominal paracentesis
5. Angiotensin converting enzyme inhibitors and angiotensin receptor blockers (as indicated, monitoring blood pressure and renal function)
6. Nonsteroidal anti-inflammatory drugs (as indicated)
7. Colloid replacement

8. Liver transplantation
9. Management of refractory ascites
    - Oral midodrine
    - Serial therapeutic paracenteses
    - Expedited referral for liver transplantation
    - Transjugular intrahepatic portosystemic stent-shunt (TIPS)
    - Peritoneovenous shunt
10. Management of spontaneous bacterial peritonitis
    - Antibiotic therapy (cefotaxime, ofloxacin)
    - Ascitic fluid testing for protein, lactate dehydrogenase (LDH), glucose, Gram's stain, carcinoembryonic antigen, and alkaline phosphatase
    - Computed tomographic scanning
11. Prevention of spontaneous bacterial peritonitis (SBP)
    - Short-term prophylaxis (norfloxacin, ceftriaxone)
    - Long-term prophylaxis (norfloxacin, trimethoprim/sulfamethoxazole)
12. Management of hepatorenal syndrome
    - Albumin infusion plus octreotide and midodrine
    - Albumin infusion plus norepinephrine
    - Expedited referral for liver transplantation
13. Management of umbilical hernias in patients with cirrhosis and ascites
    - Elective repair (during or after liver transplantation)
    - Multidisciplinary approach (with surgeon experienced in the care of patients with cirrhosis)
14. Management of hepatic hydrothorax
    - Dietary sodium restriction and diuretics
    - TIPS
15. Management of cellulitis
    - Diuretics plus antibiotics

Note: The following interventions were considered by not recommended:

Use of blood products (fresh frozen plasma or platelets) before paracentesis
Serum tested for the cancer antigen 125 (CA125) in the differential diagnosis of ascites
Percutaneous endoscopic gastrostomy in patients with cirrhosis

Major Outcomes Considered

- Accuracy of diagnostic tests
- Serum and urine levels of sodium
- Symptom control (pain, fever, fluid retention)
- Incidence of spontaneous bacterial peritonitis
- Survival rates
- Hospitalization rates
- Rates of complications from treatment or disease
- Rates of referral for liver transplantation

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

An updated Medline search from 2007-2012 was performed; search terms included ascites, hepatorenal syndrome, diet therapy, drug therapy, radiotherapy, surgery, and therapy. The search involved only papers published in English and involving humans. The search yielded 479 papers published since a similar search was performed in 2007 in preparation for writing the previous guideline on ascites.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Levels of Evidence

Level A Data derived from multiple randomized clinical trials or meta-analyses

Level B Data derived from a single randomized trial, or nonrandomized studies

Level C Only consensus opinion of experts, case studies, or standard-of-care

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Not stated

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

This guideline has been approved by the American Association for the Study of Liver Diseases and represents the position of the Association. These recommendations provide a data-supported approach. They are based on the following: (1) formal review and analysis of the recently-published world literature on the topic (Medline search); (2) American College of Physicians Manual for Assessing Health Practices and Designing Practice Guidelines; (3) guideline policies, including the American Association for the Study of Liver Diseases (AASLD) Policy on the Development and Use of Practice Guidelines and the American Gastroenterological Association (AGA) Policy Statement on Guidelines; and (4) the experience of the author in the specific topic.

Rating Scheme for the Strength of the Recommendations

Grading System for Recommendations

Class I Conditions for which there is evidence and/or general agreement that a given diagnostic evaluation, procedure or treatment is beneficial, useful, and effective

Class II Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a diagnostic evaluation, procedure, or treatment

Class IIa Weight of evidence/opinion is in favor of usefulness/efficacy

Class IIb Usefulness/efficacy is less well established by evidence/opinion

Class III Conditions for which there is evidence and/or general agreement that a diagnostic evaluation, procedure/treatment is not useful/effective and in some cases may be harmful

Cost Analysis

- Abdominal paracentesis with appropriate ascitic fluid analysis is probably the most rapid and cost-effective method of diagnosing the cause of ascites.
- The risks and costs of prophylactic transfusions may exceed the benefit.
- In comparing transjugular intrahepatic portosystemic stent-shunt (TIPS) to sequential large-volume paracentesis, one study reports prevention of hepatorenal syndrome but with higher costs in the TIPS group.
- Regular infusions of albumin for treatment of new onset or refractory ascites should be considered experimental until more studies demonstrate efficacy and cost-effectiveness.
- Intravenous ciprofloxacin followed by oral administration of this drug was found to be more cost-effective compared to intravenous ceftazidime in a randomized trial in patients who had not received quinolone prophylaxis.
- Selective intestinal decontamination with norfloxacin or trimethoprim/sulfamethoxazole in patients with prior spontaneous bacterial peritonitis (SBP) or low-protein ascitic fluid does appear to be cost-effective.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

This guideline has been approved by the American Association for the Study of Liver Diseases (AASLD) and represents the position of the Association.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate management of patients with ascites caused by cirrhosis

Potential Harms

- Complications of abdominal paracentesis have been reported in only about 1% of patients (abdominal wall hematomas), despite the fact that 71% of the patients had an abnormal prothrombin time. Although more serious complications (hemoperitoneum or bowel entry by the

paracentesis needle) occur, they are sufficiently unusual (<1/1,000 paracenteses) that they should not deter performance of this procedure.
- The chronic hyponatremia that is usually seen in patients with cirrhotic ascites is seldom morbid. Rapid attempts to correct hyponatremia in this setting can lead to more complications than the hyponatremia itself.
- Patients with parenchymal renal disease (e.g., diabetic nephropathy or immunoglobulin A nephropathy) may tolerate less spironolactone than usual because of hyperkalemia.
- Peritoneovenous shunt placement is associated with poor long-term patency, excessive complications, and no survival advantage compared to medical therapy in controlled trials.
- Clinically significant complications of diuretics include encephalopathy, serum creatinine greater than 2.0 mg/dL, serum sodium less than 120 mmol/L, or serum potassium greater than 6.0 mmol/L.
- Propranolol has been shown to shorten survival in patients with refractory ascites.
- Patients with an ejection fraction between 50% and 60% and those with diastolic dysfunction may have a higher risk of post-transjugular intrahepatic portosystemic stent-shunt (TIPS) heart failure and reduced survival.
- Systemic hypotension often complicates the use of beta blockers. Consideration should be given to discontinuing or not initiating these drugs in this setting.

Contraindications

Contraindications

Chest tube insertion is contraindicated in patients with hepatic hydrothorax.

Qualifying Statements

Qualifying Statements

Intended for use by physicians, these recommendations suggest preferred approaches to the diagnostic, therapeutic, and preventative aspects of care. They are intended to be flexible, in contrast to standards of care, which are inflexible policies designed to be followed in every case. Specific recommendations are based on relevant published information.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Mobile Device Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

Runyon BA. Management of adult patients with ascites due to cirrhosis: update 2012. Alexandria (VA): American Association for the Study of Liver Diseases; 2013 Feb. 27 p. [214 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

1998 Jan (revised 2013 Feb)

Guideline Developer(s)

American Association for the Study of Liver Diseases - Nonprofit Research Organization

Source(s) of Funding

American Association for the Study of Liver Diseases (AASLD)

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Guideline Committee

Practice Guidelines Committee

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Financial Disclosures/Conflicts of Interest

Potential conflict of interest: Nothing to disclose.

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Runyon BA, AASLD Practice Guidelines Committee. Management of adult patients with ascites due to cirrhosis: an update. Hepatology. 2009 Jun;49(6):2087-107. [174 references]

Guideline Availability

Electronic copies: Available in Portable Document Format (PDF) from the American Association for the Study of Liver Diseases Web site .

Print copies: Available from the American Association for the Study of Liver Diseases, 1729 King Street, Suite 200; Alexandria, VA 22314; Phone: 703-299-9766; Web site: www.aasld.org ; e-mail: aasld@aasld.org.

Availability of Companion Documents

This guideline is available as a Personal Digital Assistant (PDA) download via the APPRISOR™ Document Viewer from www.apprisor.com .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI on May 9, 2003. The information was verified by the guideline developer as of June 12, 2003. The guideline was updated by ECRI on July 27, 2004. The updated information was verified by the guideline developer as of August 25, 2004. This summary was updated by ECRI Institute on July 28, 2008 following the U.S. Food and Drug Administration advisory on fluoroquinolone antimicrobial drugs. This summary was updated by ECRI Institute on November 5, 2009. The information was verified by the guideline developer on December 16, 2009. This summary was updated by ECRI Institute on May 29, 2013. This summary was updated by ECRI Institute on October 25, 2013 following the U.S. Food and Drug Administration advisory on Fluoroquinolone Antibacterial Drugs. This summary was updated by ECRI Institute on May 18, 2016 following the U.S. Food and Drug Administration advisory on Fluoroquinolone Antibacterial Drugs.

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